RESPONSE TO OFFICE ACTION

I. Status of the Claims

Claims 1-4, 7, 10 and 14 - 15 are canceled. Claims 5, 6, 8, 11 and 12 are amended. Claims 5, 6, 8-9 and 11-13 are pending.

Regarding the amendments, claim 12 has been placed into independent form, and the dependencies of dependent claims revised accordingly.

II. Issues Under Section 112, First Paragraph

Regarding the new matter rejection with respect to "drug resistant leukemias," Applicants refer the Examiner to the specification at Figure 7 and Example 7, both of which demonstrate the utility of the present invention in the treatment of drug resistant leukemias, using a drug resistant HL-60 model.

Claim 7 has been canceled as duplicative.

III. Issues Under 35 USC §103(a)

It is noted that claim 12, now the only independent claim, was rejected only under the obviousness rejection set forth in item 8 of the subject Action, beginning on page 5, over Mehta *et al.* in view of O'Conner *et al.* Thus, Applicants will limit their remarks to this rejection.

In response, it is noted that the Action cites Mehta *et al.* for the proposition that it teaches "that retinoic acid increases the expression of CD38 on leukemia cells ex vivo and leukemia cell lines." This statement is not precisely true. While Mehta et al. does teach that retinoic acid will enhance expression of CD38 on drug sensitive HL-60 cells, it says just the opposite with respect

to drug-resistant HL-60R cells – it states that retinoic acid was incapable of inducing CD38 expression in HL-60R cells. It is noted that HL-60R cells are a multi-drug resistant HL-60 line. (See, *e.g.*, enclosed abstract of Notarbartolo *et al.*, 2002 and article of Terashi *et al.*, 2000, submitted 8/99, both of which clarify that HL-60R cells are recognized in the art as multidrug resistant). Thus, Mehta *et al.* clearly teaches away from applying the present invention to the treatment of drug resistant leukemias.

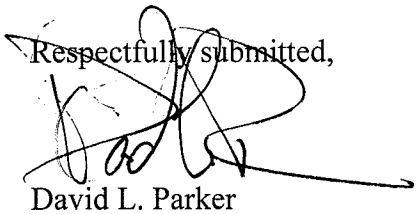
The secondary reference of O'Conner et al. does not appear to be particularly relevant to the rejection, and is certainly not relevant to the therapy of drug-resistant leukemias using an anti-CD38 immunotoxin.

For the foregoing reasons, it is believed that the claims are now free of the art.

IV. Conclusion

In view of the above amendment and remarks, Applicants believe the pending application is in condition for allowance.

Respectfully submitted,



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